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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,947	12/26/2001	Hsuan-Yin Lan-Hargest	12938-003002	8464

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EXAMINER

ZUCKER, PAUL A

ART UNIT PAPER NUMBER

1621

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,947

Applicant(s)

LAN-HARGEST ET AL.

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Current Status

1. This action is responsive to Applicants' amendment of 1 February 2006.
2. Receipt and entry of Applicants' amendment is acknowledged.
3. Claims 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 are pending.
4. Applicants have requested clarification regarding the Examiner's withdrawal of the objection to the claims set forth in the Office Action mailed 22 November 2004.
Applicants are correct that paragraph 9 was intended by the Examiner and not paragraph 5.
5. Claims 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 are finally rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making compounds in which the variable group Y^2 is $-CH_2-$ or a bond, does not reasonably provide enablement for making compounds in which the variable group Y^2 is $-CH_2-$ or a bond. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

These factors include, but are not limited to:

- a. the breadth of the claims: In the instant case the claims are extremely broad encompassing the production of a large number of organic acids;

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- b. the nature of the invention: The instantly claimed invention involves compounds which are generally considered to be unstable relative to fragments and gaseous $X_2=C=X_1$
- c. the state of the prior art: the state of the prior art in synthesis is generally considered high but would not allow one to make the unstable compounds instantly claimed;
- e. the amount of direction provided by the inventor: The inventor provides direction for the production of compounds in which Y^2 connects to the group $-C(X_1)X_2H$ via a heteroatom such as nitrogen or oxygen;
- f. the existence of working examples: The only working examples provided are directed to the production of compounds in which Y^2 is a bond or CH_2 . There are no examples in which Y^2 connects to the group $-C(X_1)X_2H$ via a heteroatom.

Compounds in which Y^2 connects to the group $-C(X_1)X_2H$ via a heteroatom are known to be inherently unstable and will decompose, under normal conditions, in the following manner : $-Y^2 C(X_1)X_2H \rightarrow -Y^2H + X_2=C=X_1$ (gas). Based upon the analysis above, the Examiner concludes that undue experimentation is required to make and use the claimed invention since the formation of these compounds is not enabled neither is their use.

Examiner's Response to Applicant's Remarks with Regard to This Rejection

6. Applicants have presented several arguments with regard to this rejection. The Examiner responds to these below:

- a. Applicants argue that the Examiner has acknowledged that Applicants have provided support for the production of compounds in which Y^2 connects to the group $-C(X_1)X_2H$ via a heteroatom such as nitrogen or oxygen. The Examiner, however, points out that this statement should have read "Applicants have provided **no** support for the production of compounds in which Y^2 connects to the group $-C(X_1)X_2H$ via a heteroatom such as nitrogen or oxygen.". The Examiner further requests that Applicants indicate where such support can be found in the specification.
- b. Applicants, further, have requested that the Examiner provide support for the contention that compounds in which Y^2 connects to the group $-C(X_1)X_2H$ via a heteroatom such as nitrogen or oxygen are unstable. In response, the Examiner directs Applicants' attention to Solomons (Page 798, lines 4-13) and further points out that this instability form the chemical basis for the well-known carbamate protecting groups such as t-BOC and FMOC. The Examiner further notes that the last proviso in claim 1 essentially requires a large portion of the claimed compounds to fall into this unstable class.

Applicant's arguments filed 1 February 2006 have been fully considered but they are not persuasive for the reasons indicated above.

7. The rejections under 35 USC § 102(b) set forth in paragraphs 10 and 11 of the previous Office Action mailed 1 November 2005 are withdrawn in response to Applicants' amendment.

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New Rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claim Rejections - 35 USC § 102

8. Claims 80-84, 86-88, 90, 91-94, 96, 97, 99, 100, 101 and 103 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Linderman et al (Journal of Organic Chemistry, Enhanced Diastereoselectivity in the Asymmetric Ugi Reaction Using a New "Convertible" Isonitrile, 1999, 64, pages 336-337). Linderman discloses (Supporting information, Page 18, last line - page 19, end) the compound **11e**, $\text{PhCH=CFCH}_2\text{CH}(\text{NH}_3\text{Cl})\text{CO}_2\text{H}$ having the double bond in trans configuration in pharmaceutically acceptable solution in D_2O (containing H_2O).

Conclusion

9. Claims 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 are pending. Claims 1-5, 7, 8, 12, 13, 16, 17, 22, 25, 26, 80-94, 96, 97 and 99-103 are finally rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


PAULA ZUCKER, PH.D.
PRIMARY EXAMINER
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